

DEC 1 9 2001

**510(k) SUMMARY****Manufacturer and Submitter**

Porex Surgical, Inc.  
15 Dart Road  
Newnan, GA 30265

Tel: (678) 479-1610  
Fax: (678) 423-1437

Contact: Howard Mercer, Ph.D.  
e-mail: howard\_mercer@porex.com

Date: November 5, 2001

Trade Name: MEDPOR® Coated Tear Drain  
Class II Device  
510(k) Number K012108

**Substantially equivalent to:**

- A. MEDPOR® Surgical Implant Material
- B. Pre-amendment borosilicate glass Jones tube

**Device description:**

The device of this submission is identical to the predicate devices except that the MEDPOR® Porous Polyethylene is formed around the glass tube.

**Indications for Use:**

An implant to bypass the obstructed lacrimal drainage system for the treatment of chronic epiphora.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DEC 19 2001

Attn: Howard Mercer, Ph.D.  
Regulatory Affairs Manager  
Porex Surgical, Inc.  
150 Dart Road  
Newnan, GA 30265

Re: K012108  
Trade/Device Name: Medpor coated tear drain  
Regulatory Class: Unclassified  
Product Code: HNL (Lacrimal System Repair Device)  
Dated: November 5, 2001  
Received: November 7, 2001

Dear Dr. Mercer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

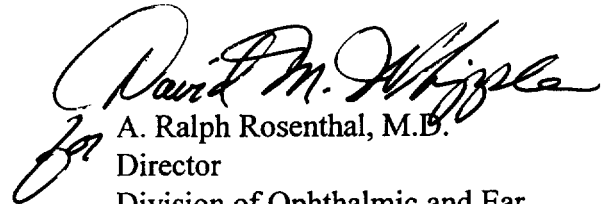
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Howard Mercer, Ph.D.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in dark ink, appearing to read "A. Ralph Rosenthal". The signature is fluid and cursive, with a large initial "A" and "R".

A. Ralph Rosenthal, M.D.  
Director  
Division of Ophthalmic and Ear,  
Nose and Throat Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

INDICATION FOR USE

Applicant: Porex Surgical, Inc.  
15 Dart Road  
Newnan, GA 30265

Tel: (678) 479-1610  
Fax: (678) 423-1437


510(k) Number: K012108

Device Name: MEDPOR® Coated Tear Drain

Indications for Use:

An implant to bypass the obstructed lacrimal drainage system for the treatment of chronic epiphora.

(PLEASE DO NOT WRITE BELOW THIS LINE)

  
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(Division Sign-Off)  
Division of Ophthalmic Ear,  
Nose and Throat Devices  
510(k) Number K012108

Prescription Use: ✓  
(Per 21CFR801.109)

OR

Over the Counter Use: \_\_\_\_\_